No. 04-579

In The Supreme Court of the United States

Supreme Court
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WAYNE CHARLES OKEN,

Petitioner,

v.

THE MONSANTO COMPANY, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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I. *Introduction*

Respondents' opposition to certiorari does not address the most compelling reason that this Court should grant the petition: Although a clear majority of lower courts agree that section 136v(b) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA"), preempts "label-based" personal injury claims against the manufacturers of registered pesticides, those courts are confused and divided about how they should scrutinize state-law design defect claims to determine whether those claims fall within that preemptive reach.

The petition explains (at 6–15) that the Eleventh Circuit's "forbidden inquiry" analysis and its holding in this case are at odds with the reasoning and analysis of those lower courts that follow the Fourth Circuit's analysis in *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747–48 (4th Cir. 1993), which holds that preemption of design defect claims turns on "whether one could reasonably foresee that the manufacturer, in seeking to avoid liability for the error, would choose to alter the product or the label." The petition also explains (at 15–16) that the Eleventh Circuit's forbidden inquiry analysis—under which states are not free even *to consider*, in going about their regulatory affairs, the adequacy of a pesticide label that has been approved by the United States Environmental Protection Agency ("EPA")—conflicts with this Court's prior holding that FIFRA section 136v(a) serves to prevent states from being preempted out of the field of pesticide regulation altogether through apparent or actual conflicts. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 607 (1991) (explaining that section 136v(a) "acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow preemptive overlap might occur").

The petition points out (at 9, 12-14) that this case is ideally suited for clarifying the confusion among the lower courts concerning FIFRA preemption because the applicable state product liability law and the factual allegations in the case squarely present the issue that has proved most vexatious to the lower courts. Under Florida law, a design defect claim can be proved either by (1) satisfying a risk-utility test, in which the adequacy of the labeling is one factor among many, or (2) satisfying a test premised on consumer expectations. Petitioner alleges that the active ingredient of a do-it-yourself lawn and garden pesticide is too dangerous to be used around residences or handled by non-professionals. This is precisely the sort of claim—a claim in which the label's substance and adequacy are relevant under state law even though the allegation is that the product's composition (in this case, the active ingredient) should have been changed—that causes so much confusion in the lower courts.

II. *Respondents' Opposition to Certiorari Does Not Undermine the Reasons for Granting the Petition*

Strikingly, Respondents' opposition to certiorari does not quarrel with any of the main points raised in the petition. Instead, Respondents present two arguments that can be described, charitably, as creative. Respondents dedicate the entire "Reasons for Denying the Petition" section of their opposition brief to an exhaustive review of evidence that was voluntarily withdrawn, although they fail to mention that it was withdrawn because it did not need to be submitted in the first instance. The only attention that the opposition pays to FIFRA preemption is in the introduction, where one discovers that "50,000 member of the plaintiffs' bar" have "urged" this Court to adopt a position on FIFRA preemption that completely prohibits personal injury actions against pesticide manufacturers (Br. in Opp. 5).

A. Respondents' Procedural Reasons for Denying the Petition Lack Merit

Respondents do not quarrel with the petition's statement of the case or the characterization of the allegations in the proceedings below. Respondents do not dispute that the thrust of Petitioner's allegations is that the active ingredient of Ortho Dursban Lawn & Garden Insect Control is too dangerous to be used by nonprofessionals and around residences; nor do they dispute that Petitioner insisted in the proceedings below that these allegations, if generally accepted as true, would cause a reasonable manufacturer to change his product (by substituting a different active ingredient) rather than the label. Instead, Respondents dedicate almost their entire brief in opposition to making much of the fact that Petitioner "voluntarily withdrew" (Br. in Opp. 2) and "affirmatively withdrew" (Br. in Opp. 12) documentary evidence and conceded the inadmissibility of an expert affidavit.

Although Respondents appear to believe that Petitioner should be especially ashamed of himself for having *voluntarily withdrawn* evidence in response to the objections of Respondent Dow AgroSciences in the proceedings in the district court, fear of losing another motion (in addition to the potentially dispositive summary judgment motion) is not the only possible explanation for this behavior, or even a sensible one. The real explanation can be found right at the outset of the opposition brief itself: "When Respondent Dow AgroSciences moved for summary judgment *on the grounds that federal law preempted [Petitioner's] personal injury claims,* [Petitioner] responded with . . . lay evidence and unauthenticated documents and one putative expert affidavit" (Br. in Opp. 2). Neither Respondent Dow AgroSciences initially, nor any Respondent subsequently, so much as hinted in a summary judgment motion that absence of a genuine issue of material

fact on causation or design defect[1] was a basis for the motion.

There was, therefore, no obligation at any point in the proceedings for Petitioner to come forth with evidence on causation or design defect. "Of course, a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Even for issues on which the nonmoving party bears the burden, the moving party must at least go to the trouble of "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325.

Neither Dow AgroSciences nor anyone else ever triggered a duty to produce evidence on causation or design defect. It is this fact, not fear of losing a much less significant motion, that explains why Petitioner chose not to litigate the admissibility of evidence that was hastily and unnecessarily produced in the first place and *voluntarily withdrew* it instead. Dow AgroSciences first made this argument—that the preemption issue is moot because Petitioner did not introduce evidence on causation and design defect in response to its summary judgment motion—to the court of appeals. Dow AgroSciences and the other Respondents are free to make the argument again on remand. It received zero attention from the panel the first time, and it is therefore undeserving of this Court's attention now. The court of appeals based its decision exclusively on FIFRA preemption, and that decision and that issue are important and are worthy of this Court's attention.

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[1] Absence of evidence of manufacturing defect and negligent manufacturing was a basis of the Dow defendants' original summary judgment motion, but that was the only factual basis of any summary judgment motion.

Contrary to Respondents' claim, this case is ready to be resolved by this Court "on the basis of the pleadings" and the existing record (Br. in Opp. 1–2). Respondents do not contest that the allegations and arguments set forth in the petition were stated below. The case comes to this Court with these allegations: Chlorpyrifos is an active ingredient contained in Dursban HF. Dursban HF was used in the formulation of Ortho Dursban Lawn & Garden Insect Control. Petitioner alleges that chlorpyrifos is too dangerous for use by nonprofessionals and use around residences. Dursban HF is also used in products that are used under professional supervision on agricultural and other nonresidential sites; Ortho Dursban Lawn & Garden Insect Control is a do-it-yourself lawn and garden pesticide. Perhaps the claim that Dursban HF is defective is inescapably an attack on the label, but even the emerging consensus among lower courts that label-based claims are preempted is important enough to warrant this Court's scrutiny. The allegation of a design defect in Ortho Dursban Lawn & Garden Insect Control, on the other hand, is not the kind that can be remedied by changing the label; it can only be remedied by changing the product's active ingredient. As the petition explained (at 14–15), and the Respondents do not challenge in their brief in opposition, the lower courts disagree on whether such a claim is preempted because of ancillary questions that a jury may be called upon to consider in the course its deliberations. The issues are well framed and ready for resolution.

B. Personal Injury Claims and Crop Injury Claims Are Not Distinguishable for Purposes of FIFRA Preemption

The Respondents' opposition to certiorari does not address the confusion among the lower courts concerning the status of certain kinds of design defect claims. The closest Respondents come to addressing this or any issue related to FIFRA preemption is in the introduction to their

brief in opposition, where Respondents sidestep the courts altogether, ignore the framing of the issue in the petition, and boldly proclaim that a consensus has been reached between pesticide manufacturers, on the one hand, and 50,000 plaintiffs lawyers on the other (Br. in Opp. 4–6). This consensus, evidenced by an *amicus* brief filed on behalf of the Association of Trial Lawyers of America ("ATLA") (and so naturally its 50,000 members) in a case now before this Court involving claims for crop damage, is that all personal injury claims against pesticide manufacturers are "label-based" because of EPA's label review process and, therefore, preempted (Br. in Opp. 4–5). Petitioner is thereby cast as an outlier or worse, given that Petitioner's counsel of record is himself a member of the Association of Trial Lawyers of America, a dissident.

Setting aside some of the statements in the opposition to certiorari regarding ATLA's *amicus* brief that are clearly over the top—whether the authors of the ATLA brief really conceded that FIFRA preempts most personal injury claims or merely assumed it for the purpose of an argument about crop damage is debatable, but even the authors of the *amicus* brief plainly did not "urge this Court to so hold," and to suggest that ATLA's "50,000 members of the plaintiffs' bar" have also "urged this Court to so hold" borders on the absurd (Br. in Opp. 5)—the authors of ATLA's *amicus* brief in support of certiorari in *Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004), do base their support of the *Bates* petition on a clear distinction between FIFRA preemption of crop injury claims and FIFRA preemption of personal injury claims. The ATLA authors reason that because EPA does not regulate efficacy, which includes harm to target crops, this Court will follow its holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (*"Medtronic"*) and hold that the claims not preempted. *See Amicus Curiae* Brief of the Association of Trial Lawyers of

America in Support of Petitioners (filed U.S. No. 03-388) at 20 (September 13, 2004).

Respondents' reliance on ATLA's position in *Bates* may be intended to suggest that ATLA's argument—that there is a clear difference for preemption purposes between crop injury claims and personal injury claims—is so *patently obvious* that there is no reason for this Court to "hold" this case, a personal injury case, and remand it to the Eleventh Circuit for reconsideration in light of *Bates*, a crop injury case. However, ATLA's argument that FIFRA preemption turns on whether EPA actually reviews data that covers the aspect of the pesticide's labeling that is suspect is not only *not obvious*, it is *completely unsupported* by the language of FIFRA and this Court's holding in *Medtronic*. The reasoning of ATLA's *amicus* brief attempts to trace *Medtronic*: "Under the similar preemption provision in the Medical Device Amendments"—the alleged similarity is more than a little suspect—"'a state law will be preempted only to the extent that the FDA has established a relevant federal 'requirement.'" *Id.* (*quoting Medtronic*, 518 U.S. at 496). ATLA rather astutely omitted an important part of the passage from *Medtronic* preceding the part it quoted, which reads: "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone* [*v. Ligget Group, Inc.*, 505 U.S. 504 (1992)], for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute." *Medtronic*, 518 U.S. at 495–96.

The preemption provision in MDA section 360k(a) is different in critical ways from FIFRA section 136v(b), most notably in its dependence on the issuance of a device-specific requirement from FDA for any actual preemption of state-imposed requirements to occur. *See Medtronic*, 518 U.S. at 498. In contrast, FIFRA section 136v(b) preempts "any requirements for labeling or packaging in addition to or

different from those required under this subchapter." In other words, FIFRA commands the EPA to regulate and establish requirements for the labeling of all pesticides, and states are absolutely forbidden from issuing any commands for labeling of their own, regardless of what the EPA has or has not considered in establishing the federal labeling requirements, regardless of whether Congress has exempted the EPA from stringent pre-approval review of certain kinds of data in establishing those requirements, and regardless of how extensive EPA's own requirements for labeling are in any given area or for any given pesticide. States simply can't impose their labeling requirements under FIFRA. Preemption under the MDA turns on whether FDA has established device-specific requirements. Preemption under FIFRA turns on whether a state-imposed duty operates as a restriction on a pesticide's use or sale (which is expressly allowed under section 136v(a)) or as a requirement for labeling or packaging (which is preempted by section 136v(b)).

The distinction between the MDA and FIFRA is obvious when one pauses to consider whether the fact that EPA does not review efficacy data prior to registration and label approval has any impact on what actions state *regulatory agencies* can take. It is highly unlikely that even ATLA would take the position that, because EPA doesn't review efficacy data for pesticides, state agencies are free to command pesticide manufacturers to place certain warnings regarding crop damage directly on the labels. Whether EPA reviews efficacy data or not, states still cannot impose positive requirements on crop damage disclosure in labeling. That is not the case with the statute at issue in *Medtronic*, where state agencies remain free to impose device-specific positive regulations absent a device-specific requirement from FDA.

The failure in general of lower courts to consider whether their FIFRA preemption analyses make sense when applied to positive enactments, or even to consider whether that matters, is the most striking feature of the FIFRA preemption landscape. Lost in the revelation that the word "requirements" in section 136v(b) applies to common-law damages actions is the fact that section 136v should not produce a greater limitation on state "regulation" by common-law damages actions than positive regulations. It is plain as day that the Eleventh Circuit's forbidden inquiry test cannot be applied to Florida's regulatory agencies. If the state of Florida takes a hard look at an EPA-approved pesticide label and decides that it doesn't do enough to protect human health, Florida is free to restrict the pesticide's use to certified applicators (section 136v(a)), although Florida is not free to command a label change (section 136v(b)). That's the plain meaning of FIFRA section 136v.

It is also plain as day that the fact that EPA does not review efficacy data has no impact on what any state agency can do. They are free to restrict uses and ban pesticides. It makes no difference at all whether the restriction or ban is for reasons related to human safety (for which EPA reviews data) or for reasons related to crop damage (for which EPA does not review data). States are not free to impose labeling requirements. It makes no difference whether the desired label requirement is intended to protect humans or to protect crops. This Court does not miss the obvious implications or potential inconsistencies of its holdings, and therefore this Court's analysis in *Bates* will impact the Eleventh Circuit's holding in this case, whether 50,000 plaintiffs lawyers see it that way or not.

III. *Conclusion*

Respondents' opposition to certiorari does not make any attempt to undercut the central arguments for granting the petition: (1) There is confusion among the lower courts about whether and when FIFRA preempts design defect claims, and (2) the factual allegations and state-law setting of this case make it an ideal instrument for resolving this confusion. Respondents opposition is remarkable only for its failure to address these points.

Respectfully submitted,

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